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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,792	12/22/2000	Donald C. Foster	99-107	1664

7590 09/21/2005

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,792

Applicant(s)

FOSTER ET AL.

Examiner

Fozia M. Hamud

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1a. Receipt of Applicants' amendment and arguments filed on 05 July 2005 is acknowledged.

Status of Claims:

1b. Claims 1-12 are pending, of which claims 1-7 are under consideration. Claims 8-12 stand withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 07/05/05:

(I) The objection of claim 1 for reciting non-elected SEQ ID Nos, is withdrawn, because said sequences are no longer recited in the claim.

(II) The rejection of claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, is withdrawn, because the rejected limitations are no longer recited.

(III). The rejection of claims 1-7 made under 35 U.S.C. §112, first paragraph, is withdrawn, because the claims are now drawn to an isolated IL-20 receptor comprising the full length IL-20RA and the full length IL-20RB. It is noted that Applicants are not disclaiming any subject matter and that they reserve the right to pursue the subject matter on a later date.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification:

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4. The specification is objected to, because although the specification contains a section entitled "Brief Description of the Drawings", (see page 2), there is no description of the 8 figures under this section. The specification describes the 8 figures, on pages 8-10. Furthermore, the specification appears to lack a section entitled "summary of the invention". It is suggested that format set forth on pages 2-3 of the office action mailed on 09 March 2005 be followed.

Claim rejections-35 USC § 112:

5. Claims 1-7 are rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for an isolated IL-20 receptor heterodimer, comprising the IL-20 R alpha subunit comprising the amino acid sequence set forth in SEQ ID NO:11 and the IL-20R beta subunit comprising the amino acid sequence set forth in SEQ ID NO:14, linked together by a peptide linker, does not reasonably provide enablement for an isolated soluble receptor comprising the IL-20 R alpha subunit comprising the amino acid sequence set forth in SEQ ID NO:11 and the IL-20R beta subunit comprising the amino acid sequence set forth in SEQ ID NO:14, or the use of a linker peptide that comprises 100 to 240 amino acid residues. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims of the instant application are drawn to a fusion protein comprising the IL-20RA and IL-20B subunits, however, claim 1 does not recite that the two subunits of IL-20R are linked by a peptide linker. Claim 2 recites that the two subunits are linked by a

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peptide linker, while claims 3 and 4 further limit the size of said linker peptide. Although claims 3 and 4 recite that the peptide linker comprises about 100 to 240 amino acid residues, (claim 3) or about 170 amino acid residues (claim 4), the instant specification discloses that the two subunits are linked using the peptide of SEQ ID NO:72, which comprises 15 amino acid residues, (see page 33, line 7). Therefore, the instant specification does not demonstrate that a peptide linker the comprises 100 to 240 amino acid residues would be effective in linking the two IL-20R subunits without interfering with the function or stability of the resulting heterodimer. Example 3 of the instant specification demonstrates that the IL-20R heterodimer binds to IL-20. Thus, the instant specification demonstrates that linking the two subunits with the peptide linker of SEQ ID NO:72 results in a heterodimer that is able to bind IL-20. The criteria set forth in *Ex parte Forman* (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the art recognizes that the selection of the peptide linker is very important for the construction of functional fusion proteins. It is well known in the art that the linker length and composition can have a great influence in the stability and the function of the resulting fusion protein. For example, Robinson et al teach that equilibrium stability varies substantially with the

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length of the peptide linker, (see Robinson et al. PNAS, Vol.95, pages 5929-5934, May 1998, see abstract). Robinson et al teach that the length of the peptide linker influences the rate of folding and unfolding of the protein, (see 5930, column 2 and bottom of page 5931), Therefore, the instant specification does not disclose that peptide linkers comprising the amino acid residues recited in claims 3 and 4 result in the desired fusion protein. The Examiner was not able to find in the relevant art the use of peptide linkers comprising 100 to 240 amino acid residues. Thus, due to the lack of direction/guidance presented in the specification regarding whether the claimed the use of linkers of the length recited in claims 3 and 4 would result in the production of IL-20R heterodimer that retains the desired activity, the complex nature of the invention, the state of the prior art the size and composition of peptide linkers plays a great role in the function of the resulting fusion protein, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim rejections-35 USC § 112, second paragraph:

6. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 1 recites in line 2 "....., wherein the IL-20RA subunit comprises a polypeptide having *an* amino acid sequence selected from the group consisting of", however, the claim recites only SEQ ID NO:11, therefore, there is no Markush group to select from. Since there is only one sequence for the IL-20RA (i.e. SEQ ID NO:11), it is suggested that the phrase "selected from the group consisting of" be deleted.

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Furthermore, since there is one polypeptide of SEQ ID NO:11, it is suggested that "...comprises a polypeptide having *an* amino acid sequence of ", be amended to recite "...comprises *the* polypeptide having *the* amino acid sequence set forth in SEQ ID NO:11". The same suggestion is made for the IL-20RB subunit. Appropriate correction is required.

6b. Claims 2-7 recite "the soluble ...; however, this limitation has been deleted from independent claim 1, accordingly the limitation lacks antecedent base. Appropriate correction is required.

6c. Claim 3 recites "about 100 to 240 amino acid residues" and claim 4 recites "...about 170 amino acid residues", however, it is unclear how long should the desired peptide linker be, 101, 150, 239 or something else. The metes and bounds of the claims cannot be ascertained.

Conclusion:

7. No claim is allowed.

Advisory Information:

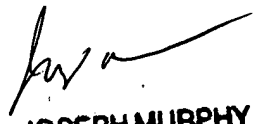
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
16 September 2005



JOSEPH MURPHY
PATENT EXAMINER